

REMARKS

The final Office Action dated February 25, 2005 has been carefully considered. Claims 1-4 and 11-12 are pending in this application. Claim 1 has been amended to more distinctly claim and particularly point out the present invention. Support for the amendment can be found in the specification at, for example, page 8, lines 2 and 5-6. No new matter has been introduced.

Entry of the amendment and reconsideration of the present application in view of the following remarks are respectfully requested.

I. CLAIM REJECTIONS UNDER 35 U.S.C. § 102(e)

Claims 1-4 and 12 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application No. 2002/0068989 to Shanley *et al.* ("Shanley"). This rejection is respectfully traversed.

The legal test for anticipation under 35 U.S.C. § 102 requires that each and every element of the claimed invention be disclosed in a prior art reference in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the public in possession of the invention. *W.L. Gore Associates v. Garlock, Inc.*, 721 F.2d 1540, 1554 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984); *In re Donohue*, 766 F.2d 531 (Fed. Cir. 1985).

Independent claim 1 as amended herein recites a "medical device for delivering a biologically active material to a body tissue of a patient in need of treatment, wherein the medical device comprises a plurality of struts; a plurality of non-structural elements integral with and projecting from the struts; and a coating comprising a biologically active material disposed on the struts and the non-structural elements." As shown in the Figures of the present application (*see e.g.* Figs. 3 and 6-14), the non-structural elements are integral with and *project from* the struts. Claims 2-4 and 12 depend upon claim 1 and therefore include all of the recitations of claim 1.

Shanley does not disclose or suggest "non-structural elements integral with and projecting from the struts" as recited in the present claims. The Examiner alleges that "Shanley discloses the invention as claimed noting figure 6 comprising: A medical device (which is a stent 10) with a plurality of struts (18) and a plurality of non-structural elements with *and projecting from* the struts (32), wherein the struts and the non-structural elements comprise the biologically active material [00038]." (*See* Office Action, p. 2). However, it is respectfully submitted that element 32 in Shanley is not a non-structural element integral with

and projecting from the strut as presently claimed. (*See, e.g.*, page 8, line 20 of the present specification, and Figs. 3 and 6-14.)

Shanley discloses that “at least one and preferably a series of openings 32 are formed at selected locations in the bridging elements 14, as shown in FIG. 6.” (Para. 0047). (emphasis added). Shanley teaches that at least some of the openings may be loaded with a beneficial agent. (Para. 0050). The openings in Shanley are formed by laser drilling or other means. (Para. 0047).

Thus, Shanley merely discloses a strut having material removed therefrom (*i.e.*, the opening) and, thus, does not disclose or suggest the inclusion of additional material that is integral with and projecting from the struts such as the non-structural elements as recited in the present claims. It is respectfully submitted that the “opening” disclosed in Shanley is not a non-structural element and cannot be considered to be a non-structural element integral with and projecting from the strut. Moreover, by disclosing an “opening” which is an absence of material, Shanley teaches away from the medical device of the present invention which includes, in addition to the struts, non-structural elements that are integral with and projecting from the struts. Even if Shanley’s openings were considered to be non-structural elements (which they are not), such openings clearly do not project from the struts. Therefore, Shanley does not disclose or suggest, and, in fact, teaches away from the use of non-structural elements integral with and projecting from the struts.

Shanley also does not disclose or suggest a coating comprising a biologically active material disposed on the struts *and* non-structural elements integral with and projecting from the strut. Shanley does not even disclose or suggest a coating on any elements that project from the struts.

Since Shanley does not disclose or suggest each and every element of the claims, it is believed that claim 1 and the claims depending thereon are patentable over Shanley. Accordingly, withdrawal of this rejection and allowance of claims 1-4 and 12, are respectfully requested.

II. CLAIM REJECTION UNDER 35 U.S.C. § 103(a)

Claim 11 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shanley in view of U.S. Patent No. 6,506,437 to Harish *et al.* (“Harish”). This rejection is respectfully traversed.

Claim 11 depends upon claim 1, and further recites that “the biologically active material is selected from the group consisting of paclitaxel, actinomycin, sirolimus, tacrolimus, everolimus, dexamethasone, halofuginone and hydrophobic nitric oxide adducts.”

Since claim 1 was shown above to be patentable over Shanley, it is believed that claim 11, which depends upon claim 1, is also patentable over Shanley. As stated above, Shanley does not disclose or suggest non-structural elements integral with and projecting from the struts; and a coating disposed on the struts and such non-structural elements as recited in the present claims.

Harish does not remedy the deficiencies of Shanley. Harish discloses a device that has depots formed in the outer surface thereof. (Col. 3, lines 32-33). Also, Harish discloses applying a composition including a therapeutic substance into the depots. (Col. 2, lines 19-20). However, the depots are not non-structural elements integral with and projecting from the struts. (*See, e.g.*, Figure 3B of present specification). The depots of Harish are not non-structural elements since they are formed from the removal or absence of material in the outer surface of the device. Such depots of Harish do not project from the struts as required by the present claims. Therefore, Harish does not disclose or suggest (1) non-structural elements integral with and projecting from the struts; and (2) a coating comprising a biologically active material disposed on the struts and such non-structural elements, as recited in the present claims.

Thus, Shanley and Harish, taken alone or in combination, do not disclose or suggest non-structural elements that are integral with and project from the struts. There is no motivation in the disclosures of Shanley and Harish to combine the teachings of these references to obtain the presently-claimed invention where Shanley and Harish both do not disclose non-structural elements that are integral with and project from the struts.

Accordingly, it is believed that claim 11 is patentable over Shanley and Harish. Thus, withdrawal of this rejection and allowance of claim 11 is respectfully requested.

III. CONCLUSION

Since all rejections to the claims are believed to be overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

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Respectfully submitted,

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Enclosures